

REMARKS

Claims 1-3 are pending in the application.

It is noted that the previous rejection under 35 U.S.C. § 102 has been withdrawn.

Claim 1-3 is rejected under 35 U.S.C. § 103 as obvious over Leahy, United States Patent No. 6,281,192. The rejection is traversed. Leahy teaches an ophthalmic composition for the treatment of dry eye, essentially a loss of tear film. The teaching of Leahy is the use of the glycoprotein mucin to relieve the symptoms of this condition. As a preservative, Leahy teaches very small amounts of various compounds, including polyhexamethylene biguanide (15 ppm). There is no teaching or suggestion in Leahy to select biguanide in preference to any of the other preservatives. Nor is there any teaching or suggestion to increase the amount of any of the compounds to the levels claimed herein, since such increased amounts would have no obvious benefit in the treatment of dry eye. An obviousness rejection cannot be based on picking and choosing from among numerous choices and then changing the amount of the selected component. Leahy provides absolutely no motivation for any such selecting or changing.

Claims 1 and 3 are also rejected under 35 U.S.C. § 103 as obvious over Ellis, United States Patent No. 6,277,365 or Tetsuhisa (JP 2000-109892). The rejection is traversed. Ellis teaches an ophthalmic composition which contains a glycoside which is said to tether an anionic therapeutic agent to the surface of the eye. Polyhexamethylene biguanide is mentioned as an optional antimicrobial agent along with a long list of other such compounds. As the Examiner has pointed out, Test Solution 2 teaches the use of 15 ppm biguanide (same amount as Leahy, *supra*), which is much less than presently claimed. The same arguments regarding Leahy are applicable here. There is no motivation in this reference to increase the levels of biguanide. Tetsuhisa also teaches an ophthalmic composition. Unlike the two earlier references, which merely did not motivate one skilled in the art to use the claimed amounts of polyhexamethylene biguanide, Tetsuhisa teaches away from such levels. Specifically, although germicides are broadly taught to be used at up to a concentration of 0.1%, biguanide is "especially desirable" at a maximum concentration of 0.001% (see paragraph [0009] of the specification).

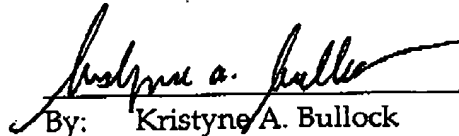
Claims 1 and 3 are also rejected under the doctrine of obviousness-type double patenting as being unpatentable over United States Patent No. 6,479,044 and co-pending application 10/224,692. These provisional rejections can be attended to when all other issues of patentability have been resolved. *Contra* to the Examiner's statement, applicants have not requested that the rejection be deferred; rather it was requested that a response to the rejections be deferred.

It is requested that the Examiner reconsider the rejections in view of these remarks.

Respectfully submitted,

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